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April 11, 2005

Commissioner for Patents  
PO Box 1450  
Alexandria, VA 22313-1450

Attn: Art Unit 3627  
Patent Examiner Steven McAllister

Re: **Application No.:** 09/849,625  
**Confirmation No.:** 9504  
**Applicants:** McGrady, et al.  
**Title:** Method of Tracking and Dispensing Medical Items  
**Docket No.:** D-1137

Sir:

Please find enclosed Applicants' Response to the Office Action dated March 25, 2005 for filing in the above identified Application.

No fee is deemed required. However, the Commissioner is authorized to charge any necessary fee associated with this Response and any other fee due to Deposit Account 10-0637.

Very truly yours,

Ralph E. Jocke  
Reg. No. 31,029

CERTIFICATE OF MAILING BY EXPRESS MAIL

I hereby certify that this document and the documents indicated as enclosed herewith are being deposited with the U.S. Postal Service as Express Mail Post Office to addressee in an envelope addressed to Commissioner for Patents, PO Box 1450, Alexandria, VA 22313-1450 this 14th day of April 2005.

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D-1137

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of	)	
<b>McGrady, et al.</b>	)	
	)	
Application No.: <b>09/849,625</b>	)	Art Unit 3627
	)	
Confirmation No.: <b>9504</b>	)	
	)	
Filed: <b>May 4, 2001</b>	)	Patent Examiner
	)	Steven McAllister
	)	
Title: <b>Method of Tracking and</b>	)	
<b>Dispensing Medical Items</b>	)	

Commissioner for Patents  
PO Box 1450  
Alexandria, VA 22313-1450

Sir:

Reconsideration and withdrawal of the species election requirement dated March 25,  
2005 is respectfully requested.

In Office Action ("Action") dated March 25, 2005 the Office again alleges species. This Action is the third such species election requirement. The first and second species election requirements have been withdrawn. Applicants respectfully submit that the current species election requirement is likewise improper.

### **The Alleged Species**

The Action alleges the following Species I-IV:

Species I: a method in which a quantity of a first medical item is provided to a patient *and* a second quantity is restocked.

Species II: a method in which a quantity of a first medical item is compounded *and* a second quantity is wasted.

Species III: a method of borrowing a second medical item from another facility.

Species IV: a method of lending a second medical item to another facility.

### **Applicants Provisionally Elect With Traverse**

In response to the Action requiring species election, Applicants, as the requirement is best understood, provisionally elect with traverse the alleged Species I. The Office acknowledges that at least claims 1-4, 23, and 24 are generic. The Office (in the Action dated December 8, 2004) previously acknowledged claim 25 as generic. Thus, as best understood, the Office acknowledges that at least claims 1-4, 23, 24, and 25 are generic.

The Action has not shown the alleged Species I to be mutually exclusive from the other alleged species II-IV. Where does the Action provide evidence that the other alleged species are prevented from being used with alleged Species I? The Office has not shown that *any* of the claims *prevent* restocking of a medical item. Which claim prevents a medical item from being restocked somewhere in the method? It follows, by inference, that *all* claims permit the providing of alleged Species I referenced in the Action. Thus, at least claims 1-10 and 15-25 are readable on alleged Species I.

Reconsideration and withdrawal of said requirement is respectfully requested. The Applicants respectfully submit that the requirement is not legally proper and should be withdrawn.

**The Requirement is not legally proper because it is not timely**

The Applicants respectfully submit that the restriction requirement in the Action dated April 21, 2004 is not in compliance with 37 C.F.R. § 1.146 which requires that a "species" restriction requirement is to be made in the first action on an application. The requirement is not in the *first* action taken in the application. In a previous Office Action, generic claims were already fully examined. Thus, the requirement is not legally proper and should be withdrawn.

**The Requirement is not legally proper because there is no serious burden**

MPEP § 803 sets forth criteria for a proper restriction requirement. One of the criteria is that there must be a "serious burden" on the examiner in order for restriction to be required.

Contrarily, if the search and examination of an entire application can be made without serious burden then the examiner must examine it on the merits.

Applicants respectfully submit that the requirement is not legally proper because the criteria for serious burden has not been met. Rather, the prosecution history is evidence that there never was a serious burden. That is, the application has already been searched, there has *already* been an examination, and the examination was on the merits. The prosecution record itself is clear evidence that there was (and continues to be) no serious burden. Furthermore, because there *already* was an examination on the merits, the species restriction requirement is in violation of 37 C.F.R. § 1.146, as previously discussed. Again, the requirement is not legally proper and should be withdrawn.

**The Requirement is not legally proper as a reasonable number of species are permitted**

Applicants are entitled to a reasonable number of species. Even if it were somehow possible for the requirement to have been timely (which it wasn't) and for the examiner to show serious burden (which he can't), 37 C.F.R. § 1.146 still permits an application to have claims directed to a reasonable number of species. Applicants respectfully submit that even if the application had species as alleged, the number of species would still be reasonable, especially in light of the Office's lack of any evidence to the contrary. Again, the requirement is not legally proper and should be withdrawn.

**The Requirement is not legally proper  
because a valid reason for species restriction is absent**

The “mutually exclusive characteristics” (MPEP § 806.04(f)) and the “relationship” (MPEP § 808.01(a)) of the alleged species have not been provided to Applicants. A valid reason why the alleged species are distinct species is absent from the Action.

In accordance with MPEP § 806.04(f), claims to be restricted to different species must be mutually exclusive. The "general test" as to when claims are restricted, respectively, to different species is the fact that one claim recites limitations which are found in a first species but not in a second species, while a second claim recites limitations only for the second species and not the first species. This is frequently expressed by saying that claims to be restricted to different species must recite the mutually exclusive characteristics of such species.

The Action has not indicated which claim recites limitations which are found in a first species but not in a second, while a second claim recites limitations disclosed only for the second species and not the first, as is required in order to meet the noted “general test” of MPEP § 806.04(f). Thus, the Action procedurally fails to present a valid reason for the requirement.

Where does the Action demonstrate that the alleged species are mutually exclusive (MPEP § 806.04(f))? For example, where does the Action show that the alleged species are prevented from being used in the same embodiment? Where does the Action provide evidence that the other alleged species are specifically prevented from be used with alleged Species I? Where does the Action provide a reason why the alleged Species I and each of the other alleged Species are mutually exclusive species? Likewise, where does the Action provide valid reasons

of mutual exclusivity for the other alleged species. The Action has not shown that each alleged specie cannot be used in an embodiment with another alleged specie. Rather, the Action's own allegations appear to be contrary to the general test for species being mutually exclusive.

The Action has not shown the alleged Species to be mutually exclusive from each other. The Action must show that each of I/II, I/III, I/IV, II/III, II/IV, and III/IV are mutually exclusive. The Action has not shown that the alleged species are prevented from being used in the same embodiment.

- I/II. The Action has not shown that the alleged species I/II are prevented from being used in the same embodiment. What prevents a method from including the restocking of a quantity (alleged Species I) and then compounding that quantity with some being wasted in the compounding (alleged Species II)?
- I/III. The Action has not shown that the alleged species I/III are prevented from being used in the same embodiment. What prevents a method from including the restocking of a *first* type of medical item (alleged Species I) along with borrowing a *second* type of medical item (alleged Species III)?
- I/IV. The Action has not shown that the alleged species I/IV are prevented from being used in the same embodiment. What prevents a method from including the restocking of a *first* type of medical item (alleged Species I) along with lending a *second* type of medical item to another facility (alleged Species IV)?

II/III. The Action has not shown that the alleged species II/III are prevented from being used in the same embodiment. What prevents a method from including the compounding of a *first* type medical item with some being wasted in the compounding (alleged Species II) along with borrowing a *second* type of medical item (alleged Species III)?

II/IV. The Action has not shown that the alleged species II/IV are prevented from being used in the same embodiment. What prevents a method from including the compounding of a *first* type medical item with some being wasted in the compounding (alleged Species II) along with lending a *second* type of medical item to another facility (alleged Species IV)?

III/IV. The Action has not shown that the alleged species III/IV are prevented from being used in the same embodiment. What prevents a method from including the borrowing a second type of medical item (alleged Species III) and then later lending that second type of medical item to another facility (alleged Species IV)?

The Action has not met the general test for mutually exclusive species. It follows that the Action has not met the test for a proper species restriction requirement. Thus, the requirement is improper and should be withdrawn.

Nor has the Office demonstrated where the alleged species occur in the claims, nor the common characteristic linking each of the alleged species. Applicants respectively disagree with the Action's allegations and descriptions of species. For these reasons it is respectfully submitted that there is no valid basis for requiring species election. Thus, it is respectfully submitted that the requirement should be withdrawn.



**The Requirement is not legally proper because it is incomplete/unclear**

The Action does not meet the species restriction requirement criteria set forth in MPEP § 809.02(a). The Action does not clearly identify each of the alleged species *to which claims are restricted* in accordance with MPEP § 809.02(a). Where does the Action state how the alleged species are directed to different embodiments? Where does the Action correspond the *claimed* subject matter to the alleged species?

For example, which claims correspond to alleged Species I by being "directed to a method in which a quantity of a first medical item is provided to a patient *and* a second quantity is restocked?" Which claims recite the step of providing a medical item to a patient? Which claims recite that a second quantity is *restocked*, especially when no claim even recites "restocked?" Likewise, which claims correspond to alleged Species IV by being "directed to a method of lending," especially when no claim even recites "lending?" Which claims respectively correspond to each of the other alleged Species? Because the criteria for proper species restriction requirement has not been met by the Office, Applicants have not been given a fair opportunity to make an informed election.

Nor is the Action clear. As previously discussed, the species election requirement relies on wording that is not recited in the claims. For example, Species I is based on language such as "is provided" and "restocked." Because the Action relies on language not recited, it is unclear whether the alleged Species I is directed to a patient taking/using a first medical item and then restocking that medical item. It follows that the Office failed to provide a disclosed example of a medical item being internally used by a patient and then restocked. Again, the Action is unclear. Nor have Applicants been given a fair opportunity to make an informed election.

The species restriction requirement does not properly describe the alleged distinct species. Nor are the alleged species clearly and properly presented. The Office has not indicated where the alleged species occur in the claims, nor the common characteristic linking the alleged species. The Action leaves Applicants the burden of properly responding to an unclear and improper requirement. Again, Applicants have not been given a fair opportunity to make an informed election. On this basis it is respectfully submitted that the requirement should be withdrawn.

The Action does not present a species restriction requirement based on the laws, rules, and Patent Office procedures. The Action at best pertains to allegations of species. The Action also appears to obfuscate the issues, because there is no proper species election requirement to be made. For these reasons it is respectfully submitted that the requirement is improper. As there is no valid basis for requiring the species election requirement, it is respectfully submitted that the requirement should be withdrawn.


Applicants, as the requirement is best understood, have provisionally elected with traverse. However, Applicants reserve all rights to change or modify their election based on the alleged species election requirement presentation being made a clearly understood and proper requirement.

### **Conclusion**

The species election requirement is respectfully traversed. The species election requirement is not proper. Therefore, it is respectfully requested that the species election requirement be withdrawn. Applicants further respectfully submit that this application is in condition for allowance.

The undersigned will be happy to discuss any aspect of the application by telephone at the Office's convenience.

Respectfully submitted,

A handwritten signature in black ink, appearing to read 'R. Jocke', written over a horizontal line.

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